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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,478	06/07/2001	John A. Peyman	JP-001	8914

7590 10/03/2003

Dr. John A. Peyman
336 West Rock Avenue
New Haven, CT 06515

EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/876,478	PEYMAN, JOHN A.	
	Examiner	Art Unit	
	Basi N Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 07 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

3. *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 4, 5 and 9, drawn to interferon-suppressing placental lactogen peptide (ISPLP) comprising the N-terminal 28 residues of hPL (SEQ ID NO:4) or derivatives, classified in class 530, subclass 350.
- II. Claims 2, 6-8 and 10 drawn to interferon-suppressing placental lactogen peptide (ISPLP) comprising the N-terminal 28 residues of hPL-1 (SEQ ID NO:7) or derivatives, classified in class 530, subclass 350.
- III. Claims 11 and 13 drawn to method for treating a human comprising administering an effective amount of a cell or tissue that has been treated ex vivo with a peptide according to claim 1 or 9, classified in class 424, subclass 93.1, for example.
- IV. Claims 12 and 14 drawn to method for treating a human comprising administering an effective amount of a cell or tissue that has been treated ex vivo with a peptide according to claim 2 or 10, classified in class 424, subclass 93.1, for example.
- V. Claims 115 and 17, drawn to a method for treating a human subject presenting with autoimmune disease, inflammatory disease or organ transplant rejection comprising administering an effective amount of ISPLP of claim 1 or 9, classified in class 514, subclass 2, for example.

- VI. Claims 16 and 18, drawn to a method for treating a human subject presenting with autoimmune disease, inflammatory disease or organ transplant rejection comprising administering an effective amount of ISPLP of claim 2 or 10, classified in class 514, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

The peptides of Invention I and II are distinct inventions because they are physically and functionally distinct chemical entities capable of separate use and manufacture. Although both peptides share some homology in the N-terminal 28 residues the critical feature required for activity has not been disclosed. Further the peptide may be used for the production of distinct antibodies which bind specifically to the peptide disclosed by the amino acid sequence SEQ ID NO:4 or SEQ ID NO:7.

The peptide Inventions I and the methods of Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide may be used for the production of antibodies.

The peptide Inventions II and the methods of Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the peptide may be used for the production of antibodies.

The peptide of Invention I are distinct from the methods of Invention IV and VI wherein the peptide of Invention I can neither be used in nor made by the methods of Invention IV and VI.

The peptide of Invention II are distinct from the methods of Invention III and V wherein the peptide of Invention I can neither be used in nor made by the methods of Invention III and V.

The methods of Inventions III-VI are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-VI would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

An election to prosecute one of the groups listed I-VI must be made. Affirmation of this election must be made by applicant in responding to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
September 30, 2003

Michael D. Pak
MICHAEL PAK
PRIMARY EXAMINER